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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-479]

Schedules of Controlled Substances: Placement of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA and 5F-CUMYL-P7AICA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes placing naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (trivial names: NM2201; CBL2201), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (trivial name: 5F-AB-PINACA), 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA, SGT-78), methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA), and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-*b*]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled

substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA.

DATES: Comments must be submitted electronically or postmarked on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference "Docket No. DEA–479" on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal

which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

- *Hearing requests:* All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement

Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Waiver of Participation in a Hearing

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR Part 1316, Subpart D. Such requests or notices must conform to the requirements of 21 CFR 1308.44(a) or (b), as applicable, and include a statement of the person's interests in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and may include a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

All requests for hearing and waivers of participation must be sent to DEA using the address information provided above.

Legal Authority

The Controlled Substances Act (CSA) provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the

Department of Health and Human Services (HHS);[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action is supported by a recommendation from the Assistant Secretary for Health of HHS (Assistant Secretary) and an evaluation of all other relevant data by DEA. If finalized, this action would make permanent the existing temporary regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA.

Background

On July 10, 2018, DEA published an order in the Federal Register amending 21 CFR 1308.11(h) to temporarily place naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (trivial names: NM2201; CBL2201), *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (trivial name: 5F-AB-PINACA), 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA, SGT-78), methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA), and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-*b*]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA) in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). 83 FR 31877. That temporary

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

scheduling order was effective on the date of publication, and was based on findings by the former Acting Administrator of DEA (Acting Administrator) that the temporary scheduling of these five synthetic cannabinoids (SCs) was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Subsection 811(h)(2) requires that the temporary control of these substances expire two years from the effective date of the scheduling order, which for these five substances had an effective date of July 10, 2018. However, this same subsection also provides that during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to a substance, the temporary scheduling of that substance may be extended for up to one year. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of HHS,[2] or on the petition of any interested party. An extension of the existing temporary order is being ordered by the Acting Administrator in a separate action, and is being simultaneously published elsewhere in this issue of the Federal Register.

The Acting Administrator, on his own motion, is initiating proceedings under 21 U.S.C. 811(a)(1) to permanently schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. DEA has gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse for these five SCs. On February 4, 2019, the Acting Administrator submitted a request to the Assistant Secretary

[2] Because the Secretary of HHS has delegated to the Assistant Secretary the authority to make domestic drug scheduling recommendations, for purposes of this proposed scheduling action, all subsequent references to "Secretary" have been replaced with "Assistant Secretary."

to provide DEA with a scientific and medical evaluation of available information and a scheduling recommendation for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, in accordance with 21 U.S.C. 811(b) and (c). Upon evaluating the scientific and medical evidence, on May 29, 2020, the Assistant Secretary submitted HHS's scientific and medical evaluation and scheduling recommendation for these five substances to the Acting Administrator. Upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, in accordance with 21 U.S.C. 811(c).

Proposed Determination to Schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA

As discussed in the background section, the Acting Administrator is initiating proceedings, pursuant to 21 U.S.C. 811(a)(1), to add NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA permanently to schedule I of the CSA. DEA has reviewed the scientific and medical evaluation and scheduling recommendation received from HHS, and all other relevant data, and conducted its own eight-factor analysis of the abuse potential of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Please note that both DEA Eight-Factor and HHS Eight-Factor analyses and the Assistant

Secretary's May 29, 2020, letter are available in their entirety under the tab "Supporting Documents" of the public docket of this action at *http://www.regulations.gov*, under Docket Number "DEA-479."

1. *The Drug's Actual or Relative Potential for Abuse*: The term "abuse" is not defined in the CSA. However, the legislative history of the CSA suggests that DEA consider the following criteria in determining whether a particular drug or substance has a potential for abuse[3]:

> *a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or*
>
> *b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or*
>
> *c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or*
>
> d) *The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community*.

In its recommendation, HHS noted that abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA has a substantial capability to create a hazard to the health of the individual users and the safety of others within the community. Adverse effects observed following the ingestion of NM2201,

[3] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

5F-AB-PINACA, or 4-CN-CUMYL-BUTINACA included diaphoresis, tachycardia, hypertension, seizures, agitation, violence, nausea, and memory impairment (see factor 6). SCs, including NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, have been generally found to be easily accessible and difficult to detect in standard urine drug screens, which contributes to their popularity and high rates of abuse.

As stated by HHS, there are no Food and Drug Administration (FDA)-approved drug products containing NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA for treatment in the United States, and there appear to be no legitimate sources for these substances as marketed drugs. In addition, HHS stated that the human use of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA is assumed to be on an individual's own initiative, rather than on the basis of medical advice from a practitioner licensed by law to administer drugs, since these SCs are not approved for medical use and are not formulated or available for clinical use. As noted by HHS, individuals may be using these five SCs on their own initiative, possibly because they are seeking the same cannabinoid-like effects as other schedule I cannabinoids while avoiding the criminal penalties associated with those substances. Further, published scientific and medical literature and law enforcement reports indicate that individuals are taking these SCs on their own initiative, rather than on the basis of medical advice of a licensed practitioner.

As stated by HHS, the pharmacological data for NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA show that these substances, similar to other schedule I SCs, bind to and activate the CB1 cannabinoid

receptors. In drug discrimination studies either sponsored by the National Institute on Drug Abuse or conducted by FDA's National Center for Toxicological Research under an Interagency Agreement, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, similar to other schedule I SCs (e.g., JWH-018, AM2201, ADB-PINACA, AB-FUBINACA), fully substitute for delta-9-tetrahydrocannabinol (THC) in animals trained to discriminate THC from vehicle control. Documented adverse effects associated with NM2201, 5F-AB-PINACA, and 4-CN-CUMYL-BUTINACA in the United States and abroad, and 5F-CUMYL-P7AICA in Europe, similar to other schedule I SCs, include tachycardia, aggressive or violent behavior, confusion, depressed mental status, severe agitation, psychosis, and/or death in some instances (see factors 4 and 6). HHS stated that because of the psychological and cognitive disturbances associated with such responses, it is reasonable to assume that these five SCs have a substantial capability to be a hazard to the health of the user and to the safety of the community.

The above information collectively indicates that the relative potential for abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA is similar to other schedule I CB1 receptor agonists.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known*: Within its recommendation, HHS described *in vitro* receptor binding and functional assays that were conducted with NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. These results indicate that NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, similar to other schedule I SCs, bind to CB1 receptors and act as full cannabinoid

agonists at CB1 receptors. Drug discrimination studies were conducted in animals to evaluate whether the five SCs have cannabinoid characteristics similar to substances in schedule I of the CSA. Each of the five SCs were shown to fully substitute for the discriminative stimulus effects produced by THC, a schedule I substance.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance*:

NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are all potent cannabinoid agonists that are pharmacologically similar to THC and several schedule I SCs.

As stated by HHS, when FDA approves a drug under the Federal Food, Drug, and Cosmetic Act for human or animal medical use, such drug is considered to have a currently accepted medical use in the United States. In the absence of such approval by FDA, a drug may be considered to have a currently accepted medical use in the United States if DEA concludes that the drug satisfies all of the following five elements:[4]

a. The drug's chemistry is known and reproducible;

b. There are adequate safety studies;

c. There are adequate and well-controlled studies proving efficacy;

d. The drug is accepted by qualified experts; and

e. The scientific evidence is widely available.

According to HHS, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA,

[4] 57 FR 10492 (1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

MMB-CHMICA, and 5F-CUMYL-P7AICA have not been approved by FDA as a human or animal drug product in the United States or, to FDA's knowledge, been approved for medical use in any other country. Moreover, there are no well-controlled clinical studies showing safety or efficacy for any of these cannabinoids. In addition, there is no evidence by qualified experts that the five cannabinoids are accepted as having therapeutic uses. Therefore, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have no currently accepted medical use for treatment in the United States.

4. *Its History and Current Pattern of Abuse*: NM2201 was first identified in the United States in November 2012 in seized drug evidence, followed by 5F-AB-PINCA (August 2013), MMB-CHMICA (December 2015), 4-CN-CUMYL BUTINACA (January 2016), and most recently 5F-CUMYL-P7AICA (February 2018). The European Monitoring Centre for Drugs and Drug Addiction reported a seizure of 50 kg of 4-CN-CUMYL-BUTINACA in Europe in 2016. According to the National Forensic Laboratory Information System[5] (NFLIS), although the first encounter of 4-CN-CUMYL-BUTINACA in the United States occurred in January 2016, the increase in encounters did not occur until later in 2017. Similarly, prior to the first encounter of 5F-CUMYL-P7AICA in the United States in February 2018, two deaths related to the use of this substance had already been documented in Europe in November and December 2016

[5] NFLIS is a DEA program and a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories in the United States. The NFLIS database also contains Federal data from U.S. Customs and Border Protection (CBP). NFLIS only includes drug chemistry results from completed analyses.

(see factor 6). The data also show that SCs originate in China and these substances are often abused in Europe and other countries before being trafficked in the United States.

HHS stated that compared to cannabis, acute fatal poisoning appears to be more prevalent with SCs. As demonstrated by NFLIS, law enforcement encounters of these five SCs have decreased following their placement in schedule I (*see Factor 5*).

5. *The Scope, Duration, and Significance of Abuse*: Following multiple scheduling actions controlling SCs, law enforcement and health care professionals have encountered novel SCs, including NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, that differ from previously scheduled SCs and one another only by small structural modifications intended to avoid prosecution while maintaining the pharmacological effects. NFLIS detailed 5,259 reports from forensic laboratories for these five substances as follows: 2,938 reports of NM2201, 1,200 reports of 5F-AB-PINACA, 797 reports of 4-CN-CUMYL-BUTINACA, 323 reports of MMB-CHMICA, and 1 report of 5F-CUMYL-P7AICA for a period from November 2012 through June 2020.[6] Reports peaked for NM2201 and 5F-AB-PINACA in 2015, for MMB-CHMICA in 2017, and for 4-CN-CUMYL-BUTINACA in 2018. The report of 5F-CUMYL-P7AICA also occurred in 2018. In addition, the System to Retrieve Drug Evidence (STRIDE)[7] and STARLiMS[8] have 644 reports involving NM2201 (311 reports), 5F-AB-PINACA (202 reports), 4-CN-CUMYL-BUTINACA (13

[6] Query date June 3, 2020.
[7] STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from DEA, other federal agencies, and some local law enforcement agencies.
[8] STARLiMS is a laboratory information management system that systematically collects results from drug chemistry analyses conducted by DEA laboratories. On October 1, 2014, STARLiMS replaced STRIDE as DEA's laboratory drug evidence data system of record.

reports), and MMB-CHMICA (118 reports) from 2013 through June 2020. A full presentation of the NFLIS and STRIDE/STARLiMS reports by substance and by year are available in the Supporting Documents of the public docket available at *http://www.regulations.gov*.

6. *What, if Any, Risk There is to the Public Health*: HHS and DEA documented multiple cases where NM2201, 5F-AB-PINACA, and 4-CN-CUMYL-BUTINACA have been identified in overdoses and/or cases involving death attributed to their abuse in the United States and abroad. In addition, HHS and DEA reported exposure to 5F-CUMYL-P7AICA resulted in two deaths in November and December 2016 in Europe. Adverse health effects reported from these incidents involving NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, and 5F-CUMYL-P7AICA included diaphoresis, tachycardia, hypertension, seizures, agitation, violence, nausea, and memory impairment, and/or death. By sharing pharmacological similarities with schedule I substances (THC, JWH-018, and other temporarily and permanently controlled schedule I SCs), NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are SCs with no approved medical use that pose serious risk to the abuser. While no adverse event information is currently available for MMB-CHMICA, substantial law enforcement seizures and the pharmacological similarity of MMB-CHMICA to other currently controlled schedule I SCs with known risks to public health (i.e., AB-CHMINACA, AB-FUBINACA, JWH-018) demonstrate an imminent hazard to public safety (see factor 5).

7. *Its Psychic or Physiological Dependence Liability*: As stated by HHS, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-

CUMYL-P7AICA have pharmacological profiles that are similar to other schedule I SCs. There are no clinical studies evaluating dependence liabilities specific to NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. HHS noted that while the five SCs are pharmacologically related to several current schedule I SCs such as JWH-018, XLR11, and AKB-48, there are still no specific studies examining their respective psychic or dependence liability. HHS stated that it is reasonable to assume, given the pharmacology of the five SCs, the likelihood of such a withdrawal effect being associated with the use of these cannabinoids as well.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA*: As noted by HHS, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are not immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. As such, DEA hereby proposes to permanently schedule NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the

analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have a high potential for abuse that is comparable to other schedule I substances such as THC and JWH-018;

2. NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have no currently accepted medical use in treatment in the United States; and

3. There is a lack of accepted safety for use of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA under medical supervision.

Based on these findings, the Acting Administrator of DEA concludes that naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (trivial names: NM2201; CBL2201); *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (trivial name: 5F-AB-PINACA); 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (trivial names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA, SGT-78); methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (trivial names: MMB-CHMICA, AMB-CHMICA), and 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-*b*]pyridine-3-carboxamide (trivial name: 5F-CUMYL-P7AICA), including their salts, isomers and salts of isomers, whenever the existence of such salts,

isomers, and salts of isomers is possible, warrant control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Requirements for Handling NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA

If this rule is finalized as proposed, NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA would continue[9] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, or who desires to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA, is required to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Security.* NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823 and in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling these five substances must also comply with the employee screening requirements of 21 CFR 1301.90-1301.93.

[9] NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 83 FR 31877, July 10, 2018.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA must be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

4. *Quota.* Only registered manufacturers are permitted to manufacture NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

5. *Inventory.* Any person registered with DEA to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA must have an initial inventory of all stocks of controlled substances (including NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records and Reports.* Every DEA registrant is required to maintain records and submit reports with respect to NM2201, 5F-AB-PINACA, 4-CN-CUMYL-

BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304 and 1312.

7. *Order Forms.* Every DEA registrant who distributes NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA is required to comply with the order form requirements, pursuant to 21 U.S.C. 828, and 21 CFR part 1305.

8. *Importation and Exportation.* All importation and exportation of NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

9. *Liability.* Any activity involving NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA not authorized by, or in violation of, the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from

review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

This proposed rule does not meet the definition of an E.O. 13771 regulatory action, and the repeal and cost offset requirements of E.O. 13771 have not been triggered. OMB has previously determined that formal rulemaking actions concerning the scheduling of controlled substances, such as this rule, are not significant regulatory actions under Section 3(f) of E.O. 12866.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. On July 10, 2018, DEA published an order to temporarily place NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA have already established and implemented the systems and processes required to handle these substances. There are currently 28 unique registrations authorized to specifically handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, or 5F-CUMYL-P7AICA, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. From a review of entity names, DEA estimates these 28 registrations represent 22 entities. Some of these entities are likely to be large entities. However, since DEA does not have information of registrant size and the majority of DEA registrants are small entities or are employed by small entities, DEA estimates a maximum of 22 entities are small entities. Therefore, DEA conservatively estimates as many as 22 small entities are affected by this proposed rule.

A review of the 28 registrations indicates that all entities that currently handle NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA also handle other schedule I controlled substances, and have established and implemented (or maintain) the systems and processes required to handle

NM2201, 5F-AB-PINACA, 4-CN-CUMYL-BUTINACA, MMB-CHMICA, and 5F-CUMYL-P7AICA. Therefore, DEA anticipates that this proposed rule will impose minimal or no economic impact on any affected entities; and thus, will not have a significant economic impact on any of the 22 affected small entities. Therefore, DEA has concluded that this proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA proposes to amend 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. In § 1308.11,

a. Add paragraphs (d)(81) through (85); and

b. Remove and reserve paragraphs (h)(31) through (35);

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(81) Naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (NM2201; CBL2201)……..7221

(82) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (5F-AB-PINACA)…….……..7025

(83) 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78)…….……..7089

(84) methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (MMB-CHMICA, AMB-CHMICA)……..7044

(85) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA)…….……..7085

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Timothy J. Shea,
Acting Administrator.

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